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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,952	01/17/2002	Patricia S. Walker	D-2933CIP	2757
33197	7590	09/16/2004	EXAMINER	
STOUT, UXA, BUYAN & MULLINS LLP 4 VENTURE, SUITE 300 IRVINE, CA 92618			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 10/051,952	Applicant(s) WALKER, PATRICIA S.	
	Examiner Chih-Min Kam	Art Unit 1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☒ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-4,6,7,9,10,12 and 36-44.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 2. NOTE: The amendment to the claims does not resolve the current issues under 35 USC 103(a). In the amendment of August 28, 2004, claim 4 has been amended. Applicants' response has been fully considered, however, claims 1-4,6,7,9,10,12 and 36-44 are rejected under 35 USC 103(a).

If applicants' amendment were entered, it would have the following response:

1. Claims 1, 2, 6, 7, 9, 10, 12, 36, 37 and 40-44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Borodic (U. S. Patent 5,183,462) in view Vadoud-Seyedi et al. (Dermatology 201, 179, September, 2000). Please see paragraph 7 of the previous Office Action dated 28 May 2004.
2. Claims 3, 4, 38 and 39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Borodic in view Vadoud-Seyedi et al. as applied to claims 1, 2, 6, 7, 9, 10, 12, 36, 37 and 40-44 above, further in view of McCabe et al. (U. S. Patent 5,525,510). Please see paragraph 8 of the previous Office Action dated 28 May 2004.

In response, applicant indicates Vadoud-Seyedi et al. disclose needless injection of a botulinum toxin into the sole of a patient's foot to treat plantar hyperhidrosis, and plantar hyperhidrosis is a condition involving excessive secretions from plantar sweat glands. Sweat glands are located in the dermal layer of the skin (e.g., see Exhibit A). Sweat glands are innervated by the sympathetic nervous system, a subset of the autonomic nervous system. Vadoud does not disclose, teach, or even suggest the use of a botulinum toxin to treat wrinkles or brow furrows; Borodic discloses administration of a botulinum toxin by injection using a syringe with a needle. Borodic does not disclose, teach, or even suggest the use of a needleless syringe to deliver a botulinum toxin for any purpose, let alone to treat wrinkles and brow furrows; a person of ordinary skill in the art would not be motivated to combine Borodic and Vadoud, as proposed by the Examiner, because Vadoud only discloses the use of a botulinum toxin to interfere with the sympathetic nervous system. In particular, Vadoud only discloses needless administration of a botulinum toxin to interfere with a neuronal influence on a sweat gland located in the dermal layer of the skin, this actually teaches away from using a needleless injection of botulinum toxin to treat wrinkles or brow furrows by reducing a muscle contraction, as recited in the present claims; as the Examiner has acknowledged, treatment of wrinkles and brow furrows is different and distinct from treatment of other conditions (see September 16, 2003 Office Action, page 3, lines 1-2); claims 3, 4, 38 and 39 are similarly unobvious from and patentable over the combination of Borodic in view Vadoud-Seyedi et al. and further in view of McCabe et al.; and each of the present dependent claims is separately patentable over the prior art because none of the prior art discloses, teach or suggest the additional features recited in the claims.

The response has been considered, however, the argument is not found persuasive because Borodic discloses the treatment of a wrinkle or brow furrows by administering a botulinum toxin using a syringe with a needle, and the secondary reference, Vadoud-Seyedi et al. teach a technique of injection using needleless syringe (e.g., a Dermojet), which has advantages, e.g., the technique is safer and the injection with pain level is acceptable. McCabe et al. teach the biological material can be coated onto the carrier such as gold beads for needleless injection. Although Vadoud-Seyedi et al. also teach using botulinum toxin to treat plantar hyperhidrosis, which is a different condition from wrinkle or brow furrows, the reference does disclose the advantages of using a Dermojet in the treatment. Furthermore, the advantage of using needleless injector (e.g., less pain, no risk of infection-safer) is well known in the art and has been stated in Bellhouse's patents (e.g., US. Patent 5,899,880, column 1, lines 61-65), which are incorporated in their entirety by reference in the specification (page 23, lines 17-26). Therefore, the motivation for a person of ordinary skill in the art to combine the references to inject a botulinum toxin with a needleless syringe for treating wrinkles and brow furrows is the advantage of using needleless injector, which is safer and less pain when compared to injection with a needle. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Continuation of 3. Applicant's reply has overcome the following rejection(s): Applicant's reply has overcome the following rejection(s): If entered, the rejection of claim 4 under 35 USC 112, second paragraph.

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issue under 35 USC 103 (a) for claims 1-4, 6, 7, 9,10,12 and 36-44.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

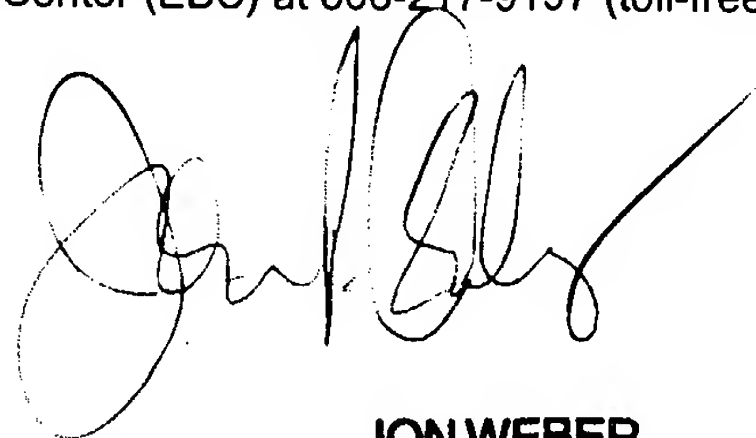
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK

CMK
September 9, 2004



JON WEBER
SUPERVISORY PATENT EXAMINER